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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,821	02/20/2004	Mohammed Shahid	VOS-048	7055

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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

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12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,821	SHAHID, MOHAMMED	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-7 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/555,038 in view of Cham et al (U.S. Patent No. 5,958,770) and Schmidt et al (U.S. Patent No. 6,242,583). The present claims are directed to a glucose-solasodine conjugates having protective groups on the glucose moiety and methods for their preparation. The claims of the copending application are directed to galactose-solasodine conjugates having protective groups on the galactose moiety and methods for their preparation. Since Cham et al disclose glucose or galactose conjugates of solasodine (columns 3 and 4) and Schmidt et al disclose various protective groups well known in sugar synthesis (column 20, lines 37-45), the substitution of protective galactose for protected glucose in the claimed compounds and

methods would have been prima facie obvious to a person having ordinary kill in the art at the time the claimed invention was made

This is a provisional obviousness-type double patenting rejection.

Applicant's arguments filed October 14, 2008 have been fully considered but they are not persuasive.

Since a terminal disclaimer has not been filed at the time of the present office action, the above stated provisional rejection has not been overcome.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cham et al (U.S. Patent No. 5,958,770) in view of Schmidt et al (U.S. Patent No. 6,242,583).

Cham et al disclose glucose conjulated of solasodine, wherein the hydroxyl geoups are substituted by acetyl (column 3 and column 4, lines 1-22) but do not disclose glucose-solasodine conjugates wherein the glucose moiety is substituted by benzoyl or a pivaloyl group. However, since Schmidt et al teach the conventional use of acetyl, benzoyl and pivaloyl groups in sugar synthesis (column 20, lines 37-45), a person having ordinary skill in the art at the time the present invention was made would have been motivated to substitute benzoyl group or pivaloyl group for the acetyl group on the compound disclosed by Cham et al because the results achieved from such a substitution would have been expected.

Applicant's arguments filed October 14, 2008 have been fully considered but they are not persuasive.

Applicant contends that changes to the compound disclosed by Cham are not suggested by Scmidt and that even if such changes were suggested, the skilled artisan would have no expectation that benzoyl or pivaloyl conjugates of solasodine would retain their biological activity. These arguments have not been found persuasive. The motivation to introduce conventional protecting groups disclosed by Schmidt on the compound disclosed by Cham is not to prodice a compound that has a biological activity but to produce an intermediate product used in a pprocess to produce the well known compounds, disclosed by Cham, having biological activity.

Claims 2 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cham et al (U.S. Patent No. 5,958,770) in view of Holick (U.S. Patent No. 5,612,317) and Scmidt et al (U.S. Patent No. 6,242,583).

Cham et al disclose glucose conjugates of solasodine (columns 3-4) but do not disclose a process for preparing said compounds by reacting solasodine with a protected glucopyranosyl donor. However, since Holick teaches a conventional method for glycosylating a closely analogous steroid derivative by reacting a steroid with a protected sugar donor (Fig. 3 and Example 1) and Schmidt et al disclose the conventional use of acetyl, benzoyl and pivaloyl protecting groups in sugar synthesis (column 20, lines 37-45), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to prepare the compounds disclosed by Cham et al using the method disclosed by Holick and conventional protecting groups

disclosed by Schmidt et al because such a person would have expected to prepare the glucose-solasodine conjugates.

Applicant's arguments filed October 14, 2008 have been fully considered but they are not persuasive.

Applicant contends that the hydroxy group of solasodine is relatively unreactive. This argument has not been found persuasive since applicant has not provided any evidence in verified form in support of said statement. Therefore, the claimed process is still seen to be a conventional glycosidation process disclosed by the art of record.

Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cham et al (U.S. Patent No. 5,958,770) in view of Ohira et al (U.S. Patent No. 6,084,081).

Cham et al disclose solamargine and glucose-solasodine conjugate (columns 3-4) but do not disclose a method of preparing solamargine from glucose-solasodine conjugate. However, since glycosylation of a sugar moiety was well known in the art at the time the present invention was made as disclosed by Ohira et al (see, for example, columns 19-20 and column 21, lines 1-8), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to prepare the compounds disclosed by Cham et al using the conventional method disclosed by Ohira et al.

Applicant's arguments October 14, 2008 have been fully considered but they are not persuasive.

Applicant contends that glycosylation of solasodine is not obvious in view of the prior art since the hydroxy group of solasodine is relatively unreactive. This argument has not been found persuasive since applicant has not provided any evidence in verified form to show that the hydroxy group of solasodine is unreactive. Applicant further contends that Ohira does not teach stereospecific B-glycosylation of solasodine requiring specific glucopyranosyl donors. This argument has not been found persuasive since applicant has not presented any evidence that the claimed process is stereospecific. Further, the motivation for introducing conventional protective groups on the compound disclosed by Cham is to produce intermediate compounds which can be used in the process for producing compounds having biological activity as disclosed by Cham.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623